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Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-390 (current) 12 VAC 5-391 (proposed)
Regulation title	Rules and Regulations for the Licensure of Hospice
Action title	Repeal of the current Promulgation of the proposed regulation
Document preparation date	Enter date this form is uploaded on the Town Hall

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

*Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Do **not** state each provision or amendment or restate the purpose and intent of the regulation.*

12 VAC 5-391 Rules and Regulations for the Licensure of Hospice is a comprehensive revision of the regulation addressing hospice programs. A hospice program provides care to meet the physical, psychological, social, spiritual and other special needs experienced during the final stages of illness, and during dying and bereavement. Because of the extensive revision to the current regulation (12 VAC 5-390), the Department chose to replace the current regulation and promulgate a new regulation in its place. To accomplish this, it is necessary to repeal the current regulation as the proposed regulation is promulgated.

Basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The regulation is promulgated by the Center for Quality Health Care Services and Consumer Protection of the Department of Health under the authority of §32.1-162.5 of the Code of Virginia, which grants the Board of Health the legal authority “to prescribe such regulation governing the activities and services provided by hospices as may be necessary to protect the public health, safety and welfare.” Therefore, this authority is mandated.

In 1998, the General Assembly adopted Senate Joint Resolution 164 (SJR164) requesting the Board of Health to begin the process of reviewing and revising the regulation governing hospice programs.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the proposed regulation is to protect and promote public health, safety and welfare through the establishment and enforcement of regulations that set minimum standards for the operation of hospice services. In addition, the purpose of the regulation is to assure quality health care through the appropriate review and inspection while protecting the right to privacy of patients without unreasonably interfering with the provision of that care. The intent of the proposed regulation is to be more reflective of the changes occurring in the industry in the last decade while providing the necessary consistency in the provision of services in order to assure safe, adequate and efficient program operation.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the “Detail of changes” section.)

As provided in § 32.1-162.12 of the Code, provisions of the proposed regulation include: i) the qualifications of the licensed and non-licensed personnel; ii) the provision and coordination of inpatient care and home treatment and services; iii) the management, operations, staffing and equipping of the hospice program; clinical and business records kept by the hospice; procedures

for the review of utilization and quality of care. In addition, the Department recognized the need to update the current regulation governing hospice programs to: (i) address in greater detail the services that are unique to the hospice program such as volunteer services, bereavement counseling, family-focused service rather than patient-centered service, palliative versus curative care, and the interdisciplinary team approach to service provision, (ii) reorganize the regulation into a user-friendlier format, and (iii) reconciling the state regulatory requirements with the federal regulations, where appropriate, to eliminate contradictions. The regulation governs the licensure of hospices except those programs “established or operated for the practice of religious tenets of any recognized church or denomination which provides care and treatment for the sick by spiritual means without the use of any drugs or material remedy” pursuant to § 32.1-162.2 of the Code of Virginia.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) other pertinent matters of interest to the regulated community, government officials, and the public.*
- If there are no disadvantages to the public or the Commonwealth, please indicate.*

The current regulation governing hospice providers was promulgated in 1990. With changes in the hospice industry, medical technology, the institution of palliative care as a valuable care option, and the Code itself, the Department recognized the need to update the regulation to be more reflective of those changes. Because services are rendered in a patient’s residence, hospice providers are not subject to the same public scrutiny as more formal health care institutions, i.e., hospitals and nursing facilities, making regulatory oversight of hospice services an important governmental function. State licensure programs provide citizens with low cost quality assurance programs that licensees are delivering quality care. However, a critical component of any license program is that the licensure standards reflect currently accepted standards of practice. Since the hospice regulation was promulgated over a decade ago, it no longer reflects “state of the art” criteria. Simply revising the current regulation, however, would not achieve the desired goal of a document that could serve as a “customer service” manual for providers while providing the necessary regulatory controls.

In 1992, the General Assembly amended the hospice program to include criminal records checks for compensated employees. That amendment rendered the regulation out of step with the requirements of the law. However, the regulation contains other needed changes, including, but not limited to: i) eliminating duplicative standards, ii) reworking archaic language, iii) expanding the licensure process explanation, and iv) including standards for infection control, pain management, and volunteer services. Passage of HB2772 of the 2003 General Assembly resolved the outstanding issue of dedicated hospice facilities, clearing the way for inclusion of facility standards and completion of the promulgation process.

Originally established as a service to individuals diagnosed with terminal cancer, today hospice providers offer services to individuals with a wide range of chronic terminal illnesses, thereby allowing those individuals to remain in their homes, where most Americans chose to spend their last days. In 2001, Last Acts, a national coalition to improve care and caring near the

end of life, published the results of their national survey ranking states on their end of life care programs. In Virginia, only 18% of terminally ill persons have access to hospice services, either because of a lack of service availability or lack of knowledge of the availability of those services.

Responsible for implementing the medical care facilities and services regulatory program, the department recognized the need for stronger standards and a more user-friendly regulation to ensure the welfare and safety of individuals receiving hospice services. Much work was necessary in order to bring the entire regulation up to currently accepted standards and practice. The approach used in developing the proposed regulation was to: i) strive for simplicity, ii) avoid being burdensome, iii) meet the requirements of the law, and iv) reflect the hospice industry's uniqueness regarding care of the terminally ill and bereavement services generally.

The primary advantage to the public and the provider community, as a result of that effort, is the enhancements made to the regulation that include:

1. Modifying the insurance or indemnity section of the regulation;
2. Adding "home visits" as part of the inspection protocol;
3. Establishing standards for dedicated hospice facilities, pain management, criminal records checks, and infection control;
4. Expanding the "General Information" section to provide better information regarding expectations of a licensed provider;
5. Implementing financial control standards and enhancing patient rights standards,
4. Adopting a biennial inspection protocol;
5. Updating the quality assurance criteria;
6. Coordinating standards to eliminate contradictions with federal certification requirements, i.e., Medicare;
7. Correcting the medical record criteria to remove mistaken references and to reflect correct record keeping practices;
8. Ensuring the regulation is clearly understandable by updating the language and eliminating ambiguities providing clearer guidance for providers; and
9. Reorganizing the regulation into a user-friendly format. The new arrangement is logical and orderly, facilitating use of the regulation.

In addition, the fees charged for licensure have been restructured. State general funds and licensure service fees fund the annual hospice licensure program. A goal of recent Administrations has been to relieve the tax burden on Virginia's citizens. One way to achieve relief is to have state licensing programs become more self-sufficient. The existing fee structure is based on a hospice program's annual budget, and do not cover the costs of the licensing program. Therefore, it is necessary to increase certain fees and establish new fees, thus relieving the taxpayer's burden via the General Fund. The proposed fee structure is based on the potential for action required by the Department regarding a program's licensure status, i.e., issuing initial and renewal licenses or as an assurance against late filing of licensure application paperwork. The late fee is designed to be an incentive to file renewal applications on time and is not charged unless a complete and accurate application is received past the due date for filing a renewal application. The renewal period is timed to coincide with the expiration of the license. If a hospice fails to file a renewal application, it runs the risk of having its license expire.

The Department acknowledges that the increases may seem dramatic, however, this is the first increase in the fees since the regulation was first promulgated in 1990. Historically, tax dollars have subsidized a disproportionate share of the hospice program and will continue to pay a major share of the cost of the program. As a further measure to alleviate the burden on the General Fund, the Department is adopting a biennial inspection protocol, i.e., each hospice program will be inspected periodically, but not less than biennially, allowing staff more time for provider consultations and technical advice to providers, and more timely responses to complaint and quality of care issues.

To determine the readiness of the proposed regulation for the public approval process and gauge its impact on providers, the Department circulated preliminary drafts to all licensed entities and interested parties. Fourteen responses were received. Since no serious concerns or potential controversies were reflected in the responses, the Department concluded general acceptance of the proposed regulation. Where necessary, adjustments in the text were made as a result of comments received. There are 75 hospice providers located statewide. The Department employs seven full-time inspectors to conduct the annual licensure inspections, process Medicare certification, and investigate complaints, as well as conducting the home care licensure and certification program. While the Department anticipates that enforcement of the regulation requires no more inspection staff at present, future revisions to the Code could very likely result in the need for additional staff and a corresponding need for additional increases in licensure fees.

No particular locality is affected more than another by this regulation. There are no disadvantages to the public, the Commonwealth, or the hospice community as a result of the proposed regulation. Every effort has been made to ensure the regulation protects the health and safety of patients receiving hospice services while allowing providers to be more responsive to the needs of their patients. Failure to implement the regulation would cause the current regulation, which is outdated and not reflective of the industry today, to remain in effect.

Financial impact

Please identify the anticipated financial impact of the proposed regulation and at a minimum provide the following information:

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	State general funds (0100) and licensure fees fund the hospice licensure program. Fees average \$47.00 per provider. The average cost to conduct an inspection is \$1300.00. In FY2001, the program budget was \$97,5000; program/subprogram: 561/03. These expenditures are on-going.
Projected cost of the regulation on localities	None, unless the locality operates a hospice program. None currently do.
Description of the individuals, businesses or other entities likely to be affected by the regulation	Hospices, small businesses or organizations doing business with a hospice program.
Agency's best estimate of the number of such entities that will be affected	Approximately 75 hospice providers

Projected cost of the regulation for affected individuals, businesses, or other entities	\$500.00 for initial or renewal licenses; other fees may be applicable. However, such fees are considered “deterrent” fees and not charged unless required.
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Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The regulation is clearly and directly mandated by law. The regulation honors the Department’s statutory charge and is the least burdensome alternative available for adequately addressing the mandate of the law. The hospice community is very supportive of the hospice regulation and licensure program as indicated by the following quote from W. R. Watts, Executive Director of the Virginia Association for Hospices:

“The needs of hospice patients are so great, and the services provided by a licensed hospice so comprehensive, that state regulation is essential to be sure that there is uniformity in provision of service, both within communities and throughout the Commonwealth. . . The integrity of the hospice concept must be protected.”

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
W.R. Watts Executive Director, Virginia Association of Hospice	Mr. Watts opined that: 1) The Department’s effort to revise the regulation [is] vital as the current regulation [is] outdated; 2) The regulation should include measures for pain management; and 3) The regulation should address “licensing of hospice facilities for residential and inpatient care.”	VDH concurs that the need to revise an outdated regulation is necessary to assure “state-of the art” criteria for the protection of individuals receiving hospice services. However, a stumbling block to completion of the revision project has the indecision the Department received from the hospice community itself regarding its desire for dedicated facility services. Until that uncertainty could be remedied, the department proceeded on a deliberative course to assure the regulation was “ready to go,” except for standards specific to dedicated facilities. The resolution occurred as a result of the 2003 General Assembly session and the passage of HB

		2772. Therefore, the Department is proceeding with the promulgation of the revised regulation.
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Impact on family

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the family unless the family utilizes hospice services.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	10	Definitions	Definitions were modified, deleted, or added to reflect the proposed document
20	20, 40, 60, 130, 140, 150	General information	Not adequate to properly inform applicants of administrative requirements for licensure; new sections added address respectively: responsibility of the department, exemption from licensure, changes to or re-issuance of a license, variances, revocation and suspension of a license, and surrender of a license
30	70	Application fee	Fees are not adequate to cover the costs of the licensing program. Fees were restructured and cover initial and renewal licenses, late fees, and license re-issue or replacement. Section realigned.
40	30, 160,	Requirements, general	Not adequate to inform applicants of expectations as a licensed provider; new sections added clarify the license process and management and administration.

50, 60	50	Initial license, License renewal	Sections consolidated to facilitate use of the regulation.
70	60	License re-issue	Section modified to reflect actual practice and logically realigned.
80, 90	80, 100	On-site inspection, Plan of correction	New sections developed to address actual practice: on-site inspections and complaint investigations
	90	N/A	New section added addressing home visits, a consumer quality of care enhancement.
	110	N/A	New section added gives direction for obtaining a criminal record check for compensated employees. Result of Code change.
	120	N/A	New section added to provide directions on establishment of dedicated facilities.
100, 110, 120	N/A	Certification of hospice, Accreditation of hospice, and Acceptance of certification and accreditation	Removed from the regulation, as the Code of Virginia does not provide for recognition of certification or accreditation in lieu of licensed, referred to a "deemed status."
130	160	Organization	The section was consolidated into section addressing management and administration of the hospice program.
140, 150	170	Governing body, Responsibilities	Sections were consolidated into one section on the Governing Body.
160	220	Insurance and bonding	Section was adjusted to remove incorrect application of law; now reflects appropriate requirements for assuring indemnity coverage and eases restrictive and overly burdensome criteria currently imposed on licensees. Section logically realigned to facilitate use of the regulation.
170	180	Administrative management	Section was realigned and updated to reflect industry standards for administering a hospice program
180	190, 200, 210	Policies and procedures	Section was realigned and language modified; two new sections added addressing financial solvency and personnel policies.
190, 200, 210, 270	190, 290	Administrative and financial controls, Personnel policies and procedures, Admission and discharge, Service policies and procedures	Sections were consolidated and appropriately realigned.
220	230	Contract services	Section was updated and ambiguities removed, section logically realigned.
230, 260	280	Medical records, record retention	Sections were consolidated, incorrect Code citation was removed; ambiguities removed and language updated.
	250	N/A	New section added to address proper and timely response to consumer complaints.
240	240	Patient rights'	Criteria modified to reflect industry standards, ambiguities were removed.

250	260	Quality assurance	Section modified to reflect current industry standards regarding improvement of services to patients. Ambiguities were removed.
	270	N/A	New section added addressing infection control.
280	300, 320, 200	Provision of services	Not adequate to inform applicants of expectations regarding the provision of hospice services. The section was divided into 3 sections to appropriately address expectations.
290	330	Plan of care	Section was consolidated into new section
	310	N/A	Regulation does not appropriately identify one of the core services of hospice care, the interdisciplinary team. The new section provides criteria identify one of the uniqueness of hospice.
300	310	Medical director required	Section updated and ambiguities removed
310, 320, 300	340	Nursing services, Registered nurses, licensed practical nurses.	Sections were consolidated to facilitate use.
340, 360	350	Nursing assistants, treatment performed by nursing assistants	Sections consolidated and updated to reflect industry standards, quality of care expectations, and eliminate contradictions with federal regulations.
350	230	Contract nursing services	Section was consolidated.
370	350	Other care attendants.	Section was consolidated.
380, 390, 400, 410, 420	360	Article 5. Social services.	Current regulation does not appropriately identify one of the core services of hospice care, social services. Sections were consolidated and updated.
430, 440	370	Article 6. Spiritual Counseling and Bereavement services	Sections were consolidated and updated.
450	300	Inpatient services	Section was consolidated.
460	400	Other special services	Section was amended.
470, 480, 490, 500, 510, 520, 530, 540, 550	370	Article 2. Physical therapy services; Article 3. Occupational therapy; Article 4. Speech Therapy	Sections were repetitive and duplicative; sections were consolidated
560, 570, 580	380	Article 5. Specialized nutrition support	Sections were consolidated and updated.
590, 600, 610, 620	430	Article 6. Intravenous therapy services	Sections were consolidated and updated.
630, 640, 650, 660	420	Article 7. Respiratory Therapy Services	Sections were consolidated and updated.
	440, 450, 460, 470, 480, 490, 500	N/A	Current regulation does not include standards dedicated hospice facilities, new sections were added respectively addressing: general facility requirements, required staffing, pharmacy services, restraints, food services, laundry services, and pet care.

